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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/037,795

01/03/2002

John A. Krueger

SPEC - 6137

6948

7590

07/14/2004

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,795

Applicant(s)

JOHN KRUEGER

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements filed 5/1/02 and 5/29/03 comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. They have been placed in the application file, and the information referred to therein has been considered by the examiner as to the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,669,882 to Pyles.

In regards to claim 1, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening.

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3. Claims 1, 4, 5, 6, 9, 10 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,558,353 to Zohmann.

In regards to claims 1, 4, 5, 6, 9, 10 and 11, Zohmann discloses a biopsy system capable of obtaining a bone marrow sample including an outer cannula (70); a handle portion (60) coupled to the end of the outer cannula (Col. 7, lines 40 – 41); the outer cannula is adapted to removably accommodate a biopsy aspiration device (50) therein (Col. 7, lines 27 – 28). The aspiration device includes an elongated cannula body having a proximal end (51), a distal tip (54) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body (Col. 6, line 45), the lumen terminating at a proximal opening (53) and terminating at a single laterally oriented distal opening immediately adjacent the distal tip; wherein the tip of the cannula body comprises an arcuate curved surface (Col. 6, lines 45 – 46) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. The proximal end of the aspiration device includes viewable indicia to indicate the position of the laterally oriented distal opening (Col. 7, lines 14 – 17). Zohmann discloses a stylet for removable insertion within the outer cannula (Col. 5, lines 49 – 52).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,314,565 to Lee in view of U.S. Patent No. 5,292,3310 to Yoon.

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In regards to claims 12 and 14, Lee discloses a method for obtaining a bone marrow sample from a marrow site in a patient including penetrating the cortex of a bone with an outer cannula having a stylet positioned within (Col. 5, lines 51 – 53), the distal portion of the stylet extending beyond the end of the outer cannula, until the distal end is surrounded by marrow; removing the stylet (Col. 5, line 54); inserting into the outer cannula a biopsy aspiration device such that the distal tip of the aspiration device is extended into marrow. Lee discloses attaching an aspiration source to the proximal end of the aspiration device and withdrawing a sample of marrow from the sampling site (Col. 5, lines 55 – 59). Lee discloses removing the aspiration device from the outer cannula and advancing the outer cannula into the bone to obtain a core sample (Col. 5, lines 62 – 65). Lee discloses the aspiration device including an elongated cannula body having a proximal end, a distal tip, a linear longitudinal axis and a lumen running longitudinally through the interior of the cannula body (Col. 5, lines 12 – 16). However, Lee fails to disclose the lumen terminating at a proximal opening and at a single laterally oriented distal opening immediately adjacent the distal tip; wherein the tip of the cannula body comprises an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. Yoon discloses an aspiration system including an elongated cannula body (32) having a proximal end, a distal tip (38), a linear longitudinal axis and a lumen running longitudinally through the interior of the cannula body. The lumen terminates at a proximal opening and at a single laterally oriented distal opening (36) immediately adjacent the distal tip (38). The tip of the cannula body comprises an arcuate curved surface (37) originating on the opposite side to the laterally oriented distal opening (36), the curved surface terminates at the distal-most point (38) of the distal opening (Col. 4, lines 39 – 46). It would have been obvious to one having ordinary skill in the art to modify the aspiration device as taught by Lee to include a cannula having a lumen terminating at a

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proximal opening and at a single laterally oriented distal opening immediately adjacent the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Yoon in order facilitate precise penetration and positioning of the aspiration device while reducing tissue compression (Col. 9, lines 34 – 36).

6. Claims 1 – 3, 6 – 8 and 11 - 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,478,751 to Krueger et al. in view of U.S. Patent No. 5,669,882 to Pyles.

In regards to claims 1 – 3, 6 – 8 and 11, Krueger et al. discloses a bone biopsy system having including an outer cannula (16); a handle portion (12) coupled to the end of the outer cannula; the outer cannula is adapted to removably accommodate a biopsy aspiration device (80) therein (Col. 7, lines 3 – 4). The aspiration device includes an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (93) adjacent to the tip. The proximal end of the cannula body comprises a luer attachment for removable coupling of an aspiration source (Col. 6, lines 50 – 54). Krueger et al. discloses a stylet (14) for removable insertion within the outer cannula (16; Col. 4, lines 60 – 61). However, Krueger et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the laterally oriented distal opening and terminating at the distal-most point of the distal opening. However, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line

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19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Lee to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the patient (Col. 4, lines 5 – 8).

In regards to claims 12 – 14, Krueger et al. discloses a method for obtaining a bone marrow sample from a marrow site in a patient including penetrating the cortex of a bone with an outer cannula having a stylet positioned within (Col. 7, lines 17 – 20), the distal portion of the stylet extending beyond the end of the outer cannula, until the distal end is surrounded by marrow; removing the stylet (Col. 7, line 22); inserting into the outer cannula a biopsy aspiration device such that the distal tip of the aspiration device is extended into marrow (Col. 7, lines 25 – 26). Krueger et al. discloses attaching an aspiration source to the proximal end of the aspiration device and withdrawing a sample of marrow from the sampling site (Col. 7, lines 26 – 31). Krueger et al. discloses rotating the aspiration device within the outer cannula thereby repositioning the laterally oriented distal opening (Col. 7, lines 47 – 52). Krueger et al. discloses removing the aspiration device from the outer cannula and advancing the outer cannula into the bone to obtain a core sample (Col. 7, lines 55 – 59). Krueger et al. discloses the aspiration device including an elongated cannula body (82) having a proximal end (84), a distal tip (91) and a linear longitudinal axis; a lumen running longitudinally through the interior of the cannula body. The aspiration device includes a distal tip and a laterally oriented distal opening (93) adjacent to the tip. However, Krueger et al. fails to disclose the distal tip having an arcuate curved surface originating on the opposite side to the

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laterally oriented distal opening and terminating at the distal-most point of the distal opening.

However, Pyles discloses an elongated cannula body (14) having a proximal end (20), a distal tip (16) and a linear longitudinal axis; a lumen (18) running longitudinally through the interior of the cannula body (Col. 3, lines 25 – 26), the lumen terminating at a proximal opening (22) and terminating at a single laterally oriented distal opening (48) immediately adjacent the distal tip (Col. 4, lines 2 – 3); wherein the tip of the cannula body comprises an arcuate curved surface (Col. 3, line 19) originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening. It would have been obvious to one having ordinary skill in the art to modify the distal tip of the aspiration device as taught by Lee to include an arcuate curved surface originating on the opposite side to the laterally oriented distal opening, the curved surface terminating at the distal-most point of the distal opening as taught by Pyles in order to allow for rotation of the needle during use with a decreased chance of cutting the tissue of the patient (Col. 4, lines 5 – 8).

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 4,645,491 discloses a cannula having a laterally oriented opening adjacent a curved distal tip.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on (703) 308-3400. The fax phone numbers for the organization

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where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

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JMLF

July 12, 2004


MARY BETH JONES
ACTING SUPERVISORY PATENT EXAMINER